

We claim:

1. A method for determining the integrated glycemic condition of a subject using a single test system, consisting of the steps of:

- 5 (a) measuring the concentration of glucose in a sample of whole blood from a subject;
- (b) measuring the concentration of protein-bound glucose in a sample of whole  
10 blood from the subject, wherein the glucose concentration is indicative of the immediate glycemic condition and wherein the protein-bound glucose concentration is indicative of either  
15 intermediate or long-term glycemic condition; and
- (c) optionally, measuring the concentration  
20 of another analyte indicative of glycemic condition in a sample of whole blood from the subject.

2. A method for determining the integrated glycemic condition of a subject using a single test system, consisting of the steps of:

- 5 (a) measuring the concentration of glucose in an unprocessed body fluid sample from a subject;
- 10 (b) measuring the concentration of protein-bound glucose in an unprocessed body fluid sample from the subject, wherein the glucose concentration is indicative of the immediate glycemic condition and wherein the protein-bound glucose concentration is indicative of either intermediate or long-term glycemic condition; and
- 15 (c) optionally, measuring the concentration of another analyte indicative of glycemic condition in an unprocessed
- 20 body fluid sample from the subject.

3. The method of claim 2, wherein the protein-bound glucose is fructosamine which indicates intermediate glycemic condition.

25 4. The method of claim 2, wherein the protein-bound glucose is selected from the group consisting of total glycated hemoglobin and Hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>), any one of which indicates long-term glycemic condition.

5. The method of claim 2, wherein the protein-bound glucose is selected from the group consisting of total glycated serum protein and glycated albumin, any one of which indicates intermediate glycemic condition.

5 6. The method of claim 2, wherein more than one protein-bound glucose is measured.

7. The method of claim 2, wherein the unprocessed body fluid sample of step 2(a) and the  
10 unprocessed body fluid sample of step 2(b) are whole blood.

8. The method of claim 2, wherein the unprocessed body fluid sample of step 2(a) and the unprocessed body fluid sample of step 2(b) are separate body fluid samples.

15 9. The method of claim 2, wherein another analyte which is indicative of glycemic condition, which can optionally be measured in step 2(c), is selected from the group consisting of a ketone body, a fatty acid derivative, and microalbumin.

20 10. The method of claim 9, wherein the ketone body is selected from the group consisting of acetone,  $\beta$ -hydroxybutyrate, acetoacetate.

11. The method of claim 2, wherein the step of measuring the concentration of glucose of step 2(a) comprises:

- 5 (a) providing a test device containing a signal producing system capable of signalling the concentration of glucose present in an unprocessed body fluid sample;
- 10 (b) applying the unprocessed body fluid sample to the test device; and
- 15 (c) determining the concentration of glucose present in the unprocessed body fluid sample applied to the test device with an apparatus having an automatic glucose concentration determining means that is responsive to the signal produced in step 11(a), the apparatus further having the automatic determining means coupled to a display means and further having a receiving port in connection with the automatic determining means.
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12. The method of claim 2, wherein the step of measuring the concentration of protein-bound glucose of step 2(b) comprises:

- 5 (a) providing a test device containing a signal producing system capable of signalling the concentration of protein-bound glucose present in an unprocessed body fluid sample;
- 10 (b) applying the unprocessed body fluid sample to the test device; and
- 15 (c) determining the concentration of protein-bound glucose present in the unprocessed body fluid sample applied to the test device with an apparatus having an automatic protein-bound glucose concentration level determining means that is responsive to the signal produced in step 12(a), the apparatus  
20 further having the automatic determining means coupled to a display means and further having a receiving port in connection with the automatic determining means.

13. A method for determining the integrated glycemic condition of a subject using a single test system, consisting of the steps of:

- 5 (a) measuring the concentration of glucose in an unprocessed body fluid sample from a subject;
- 10 (b) measuring the concentration of protein-bound glucose in an unprocessed body fluid sample from the subject, wherein the glucose concentration is indicative of the immediate glycemic condition and wherein the protein-bound glucose concentration is indicative of either intermediate or long-term glycemic condition; and
- 15 (c) measuring the concentration of another analyte indicative of glycemic condition in an unprocessed body fluid sample from the subject.
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14. A method of diagnosing diabetes in a subject using a single test system, consisting of the steps of:

- (a) obtaining at least one unprocessed body fluid sample from a subject;
- 5 (b) measuring the concentration of glucose in an unprocessed body fluid sample from the subject wherein the glucose concentration is indicative of the immediate glycemic condition;
- 10 (c) measuring the concentration of protein-bound glucose in an unprocessed body fluid sample from the subject, wherein the protein-bound glucose concentration is indicative of either intermediate or  
15 long-term glycemic condition; and
- (d) comparing the measured concentration of glucose from step 14(b) and the measured concentration of protein-bound glucose from step 14(c) to the  
20 glucose concentration level and the protein-bound glucose concentration level of a normal subject, wherein elevated concentrations of glucose and protein-bound glucose above  
25 levels of a normal subject are diagnostic of diabetes.

15. The method of claim 14, wherein at least one unprocessed body fluid sample of step 14(a) is whole blood.

16. A single test system for determining the integrated glycemic condition of a subject, consisting of:

- (a) a means for measuring the concentration of glucose;
- 5 (b) a means for measuring the concentration of protein-bound glucose; and
- (c) optionally, a means for measuring the concentration of another analyte indicative of glycemic condition.

10 17. The test system of claim 16, wherein the means for measuring a concentration of glucose of step 16(a) comprises:

- 15 (a) a test device containing a system capable of signalling the concentration of glucose present in an unprocessed body fluid sample from a subject; and
- (b) an apparatus having a receiving port capable of receiving the test device and further having an automatic glucose concentration determining means responsive to the signal produced in  
20 step 17(a) coupled to the receiving port, the apparatus further having a display means coupled to the automatic determining means.  
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18. The test system of claim 17, wherein the signal producing system includes reagents to produce a glucose oxidase enzyme reaction.



19. The test system of claim 17, wherein the automatic determining means is a spectrophotometer.

20. The test system of claim 19, wherein the spectrophotometer measures one of the following selected  
5 from the group consisting of reflectance, fluorescence, absorbance, and transmittance.

21. The test system of claim 17, wherein the automatic determining means is an electrochemical sensor.

22. The test system of claim 16, wherein the  
10 means for measuring a concentration of protein-bound glucose of step 16(b) comprises:

(a) a test device containing a system capable of signalling the concentration of protein-bound glucose present in an  
15 unprocessed body fluid sample from a subject;

(b) an apparatus having a receiving port capable of receiving the test device and further having an automatic  
20 protein-bound glucose concentration determining means responsive to the signal produced in step 22(a) coupled to the receiving port, the apparatus further having a display means coupled  
25 to the automatic determining means.

23. The test system of claim 22, wherein the automatic determining means is a spectrophotometer.

24. The test system of claim 23, wherein the spectrophotometer measures one of the following selected from the group consisting of reflectance, fluorescence, absorbance, and transmittance.

5           25. The test system of claim 22, wherein the protein-bound glucose is fructosamine and wherein the test device containing the signal producing system comprises:

10                   (a) a liquid-permeable buffer layer containing a buffer having a pH value of at least 9;

                 (b) an indicator layer containing an indicator capable of being reduced by fructosamine; and

15                   (c) a support member optionally having a detection aperture; wherein the buffer layer is adjacent the indicator layer and wherein the buffer layer and indicator layer are supported by the support member.

20           26. The test system of claim 25, wherein the test device containing the signal producing system further comprises one or more additional layers in fluid contact with the buffer layer.

25           27. The test system of claim 26, wherein the additional layers are selected from the group consisting of a blood cell separation layer, a radiation blocking layer, an interference removal layer, a contamination prevention layer, a dialysis layer, a filtering layer, and a support layer.

28. The test system of claim 27, wherein the additional layer is an additional support member having a sample aperture and wherein the buffer layer and the indicator layer are positioned between the support members.

5           29. The test system of claim 28, wherein the buffer layer is superposed above the dye layer.

30. The test system of claim 25, wherein the buffer layer and the dye layer are juxtaposed.

10           31. The test system of claim 22, wherein the protein-bound glucose is fructosamine and wherein the test device containing the signal-producing system comprises:

- 15           (a) a first plastic substantially planar support member having a sample aperture;
- (b) a second plastic substantially planar support member having a detection aperture;
- (c) a whole blood separation layer;
- 20           (d) a liquid permeable buffer layer containing a buffer having a pH value of between about 10 and about 12; and

5 (e) an indicator layer containing a  
nitroblue tetrazolium dye, wherein the  
separation layer is superposed above  
the buffer layer and the buffer layer  
is superposed above the indicator layer  
and wherein the separation layer, the  
buffer layer and indicator layer are  
positioned between the first support  
member and the second support member,  
10 all in fluid contact with the adjacent  
layer.

32. A method for analyzing the concentration of  
fructosamine in a body fluid sample of a subject wherein  
the total measuring time required is less than or equal to  
15 five (5) minutes, with the proviso that no reaction  
accelerator is present.

33. The method of claim 32, wherein the analysis  
is carried out at ambient temperature.

34. The method of claim 32, wherein the total  
20 measuring time required is less than or equal to four (4)  
minutes.

35. The method of claim 32, wherein the the  
total measuring time required is less than or equal to  
three (3) minutes.